UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

1) THE CHEROKEE NATION,

Plaintiff,

-against-

1) JOHNSON & JOHNSON;
2) JANSSEN PHARMACEUTICALS, INC.;
3) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;
4) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.,

Defendants.

JURY TRIAL DEMANDED

COMPLAINT

1. The Cherokee Nation, through Attorney General Sara Hill, brings this civil action for injunctive relief, compensatory damages, punitive damages, civil penalties, and any other relief allowed by law against the Defendants that, by their actions, have knowingly or negligently marketed and promoted prescription opioid drugs and have knowingly or negligently manufactured and distributed prescription opioid drugs within the Cherokee Nation in a manner that foreseeably injured, and continues to injure, the Cherokee Nation and its citizens.

2. There is a devastating epidemic of prescription opioid abuse sweeping through the Cherokee Nation and across the United States. It is an epidemic of unprecedented proportions, leaving in its wake a substantial loss of public and private resources and heartbreaking addiction,

disability, and death. Indeed, on October 26, 2017, the President of the United States declared the opioid epidemic a public health emergency.[1]

3. Today in the Cherokee Nation, and everywhere else in the country, prescription opioids kill more people than heroin. The National Center for Health Statistics reported that prescription opioids killed 22,598 people in the United States in 2015, as compared to 12,989 deaths from heroin. Prescription opioids are the driving force behind skyrocketing rates of drug overdose deaths, which now surpass car accident deaths nationwide. And as the former U.S. Surgeon General stated during his 2016 visit with tribal representatives in Oklahoma – where most Cherokee Nation citizens reside – the "prescription opioid epidemic that is sweeping across the U.S. has hit Indian country particularly hard."

4. In 2016 alone, over 326 million opioid pills were dispensed to Oklahoma residents, including citizens of the Cherokee Nation, enough for every adult to have 110 pills. Oklahoma dispenses the most prescription fentanyl per capita.

5. The brunt of the epidemic could have been, and should have been, prevented by the Defendant companies. Yet despite all of the known dangers of opioid drugs they have produced, the Defendants have employed long-running, deceptive, and deceitful marketing campaigns, advocating for the drugs' expanded use while downplaying or outright misstating the dangers of opioid drugs, and by allowing opioids to be diverted into improper channels to fuel the epidemic. Those efforts have led to billions of dollars in profits for Defendants – but at a terrible cost to the Cherokee Nation, which has become flooded with prescription opioids and has had to incur the costs of increased health care expenditures, crime, and social ills resulting from prescription opioid abuse, addiction, and diversion.

[1] Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds*, N.Y. Times (Oct. 26, 2017), https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html.

6. Opioids have been a commercial triumph for Defendants, one born out of canny marketing. Defendants have profited handsomely from improperly marketing prescription opioids to an ever-growing population of physicians and patients for a range of pain relief. They have done so while obscuring the fact that prescription opioids are dangerous and addictive when used for general pain management and relief. Defendants deliberately pressed a narrative about opioids that was bereft of scientific support to encourage the use of opioids by those suffering from common chronic pain conditions.

7. Defendants' years-long marketing campaign advocating for the prescription of opioid drugs to treat a large range of chronic pain – despite scientific and medical findings that cautioned against using opioids for such pain – has led to the vast overprescription and widespread distribution of prescription opioids. Those overprescribed opioids are the drugs that have fueled the opioid epidemic in the Cherokee Nation.

8. Defendants also have failed in their role as the first gatekeepers in the controlled substance distribution chain. Each registered party in that chain has a duty to serve as a "check" in the drug delivery system by securing and monitoring opioids at every step as they travel through commerce, protecting them from theft, and refusing to fill suspicious or unusual orders by downstream distributors, pharmacies, and patients. Defendants have habitually turned a blind eye to known or knowable problems in their own supply chain.

9. By doing so, Defendants created conditions in which vast amounts of opioids have flowed freely from their manufacturing facilities to wholesale distributors, fed through doctors and retail pharmacies, and on to abusers and drug dealers, with Defendants filling suspicious orders from distributors and pharmacies while consciously ignoring "red flags" in the

amount and concentration of orders for opioids that require further investigation and resolution before distributing the pills into the regulated controlled-substances supply chain.

10. This kind of behavior by Defendants has allowed massive amounts of opioid pills to be diverted from legitimate channels of distribution into the illicit black market in quantities that have fueled the opioid epidemic in the Cherokee Nation. This is the phenomenon known as "opioid diversion." Acting against their common law duties, through both illegal marketing and opioid diversion, Defendants have created an environment in which drug diversion can flourish. As a result, unauthorized opioid users in and around the Cherokee Nation have ready access to illicit sources of diverted opioids.

11. For years, Defendants and their agents have had the ability to substantially reduce the death toll and adverse economic consequences of their illegal marketing and diversion of opioids in the Cherokee Nation, but chose to pursue corporate profits instead. Defendants have not stopped their continuous pursuit of opioid profits through improper and illegal means.

12. Defendants have caused foreseeable damages to the Cherokee Nation, including the costs of providing: (1) medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) counseling and rehabilitation services; (3) treatment of infants born with opioid-related medical conditions; (4) welfare for children whose parents suffer from opioid-related disability or incapacitation; (5) law enforcement and public safety relating to the opioid epidemic within the Cherokee Nation; and (6) increased crime, property damage, and public blight within the Cherokee Nation caused by opioids. The Cherokee Nation has also suffered substantial damages relating to the lost productivity of Cherokee Nation citizens and businesses.

PARTIES

I. Plaintiff

13. The Cherokee Nation is a federally recognized sovereign Indian nation. It is governed by the Cherokee Nation Constitution and the laws of the Cherokee Nation, and exercises inherent governmental authority within the Cherokee Nation.

14. The Cherokee Nation is comprised of approximately 355,000 citizens. Of these, approximately 177,000 reside within the Tribal Jurisdictional Service Area ("TJSA"). Cherokee Nation citizens comprise a significant percentage of the population in the counties within the TJSA.

15. This TJSA encompasses the whole or part of 14 Oklahoma counties – Adair, Cherokee, Craig, Delaware, Mayes, McIntosh, Muskogee, Nowata, Ottawa, Rogers, Sequoyah, Tulsa, Wagoner, and Washington – all in northeastern Oklahoma.

16. Cherokee Nation Attorney General Sara Hill brings this action in the exercise of her powers on behalf of the Cherokee Nation in its proprietary capacity and under its *parens patriae* authority in the public interest to protect the health, safety, and welfare of all Cherokee Nation citizens. In particular, Attorney General Hill brings this action to stop the growing prescription opioid epidemic within the Cherokee Nation and to recover damages and seek other redress for harm caused by Defendants' improper marketing and promotion practices relating to prescription opioids and by Defendants' improper manufacturing, distribution, and reporting practices relating to prescription opioids. Defendants' actions have caused and continue to cause a crisis that threatens the health, safety, and welfare of the citizens of the Cherokee Nation.

II. Defendants

17. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

18. Defendant Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

19. At all relevant times, Jansen Pharmaceuticals, Inc., Johnson & Johnson, Janssen, Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein. They are collectively referred to as "Johnson & Johnson" or as "Defendants."

JURISDICTION

20. Count Four (Unjust Enrichment) presents a federal common law claim. This Court therefore has jurisdiction under Article III, Section 2 of the United States Constitution.

21. The remaining Counts present state-law claims over which this Court has supplemental jurisdiction. *See* 28 U.S.C. § 1367.

22. This Court has jurisdiction over Defendants because Defendants conduct business in the TJSA and throughout Oklahoma, and have deliberately engaged in significant acts and omission within Oklahoma that have injured the Cherokee Nation and its citizens. Defendants purposefully directed their activities at Oklahoma, specifically the Cherokee Nation and its citizens, and the claims arise out of those activities.

23. In addition, this Court has personal jurisdiction over Defendants, each of which has substantial contacts and business dealings throughout the Cherokee Nation and Oklahoma by virtue of their marketing, sales, manufacturing, and distribution of prescription opioids within the Cherokee Nation territorial and political jurisdiction.

24. Venue is proper in this District pursuant to §1391(b).

I. Causes of Action Arising in the Tribal Jurisdictional Service Area ("TJSA")

25. The TJSA is recognized in federal, state, and tribal law as the territorial area of the Cherokee Nation established by prior treaties between the United States and the Cherokee Nation.

26. This TJSA encompasses the whole or part of 14 Oklahoma counties – Adair, Cherokee, Craig, Delaware, Mayes, McIntosh, Muskogee, Nowata, Ottawa, Rogers, Sequoyah, Tulsa, Wagoner, and Washington – all in northeastern Oklahoma, as shown on the map attached as Exhibit A, entitled "Tribal Jurisdictions in Oklahoma" prepared by the State of Oklahoma Department of Transportation.[2]

27. The Cherokee Nation has approximately 355,000 citizens. Of these, approximately 177,000 reside within the TJSA. Cherokee Nation citizens comprise a significant percentage of the population in these counties.

28. The TJSA is widely recognized in federal law as territory in which the Cherokee Nation has governmental authority to administer a variety of federal programs and to exercise sovereign rights.

29. For example, the Cherokee Nation has the authority under the Indian Self-Determination Act to enter into annual self-governance compacts and funding agreements to run Bureau of Indian Affairs' programs located throughout the TJSA where such programs are of "special . . . significance" to the Nation. *See* 25 C.F.R. §§ 1000.125-.126; 25 U.S.C. §§ 5384-85. The 2006 Compact between Indian Health Service and the Cherokee Nation, for instance, in a section titled "Territorial Jurisdiction of the Cherokee Nation," describes "the boundaries of the

[2] Also available at http://www.ok.gov/health2/documents/map_tribal_jurisdictions.pdf

Cherokee Nation territory" as the areas set by the patents of 1838 and 1846, as modified, and further describes the Cherokee Nation "service area" under the Compact as "within all or part of a fourteen county area located in the Claremore and Tahlequah Service Units of the Oklahoma City Area Indian Health Service." *See* 2006 Compact §1.3.

30. The federal government has authorized the Cherokee Nation to receive federal funding to support the exercise of "tribal control in all matters relating to the education of Indian children" within the TJSA. 25 U.S.C. § 2020(d)(1).

31. Federal law authorizes the Nation to implement federal grants within the TJSA where such grants further the development and support of tribal courts exercising jurisdiction within the jurisdictional territory. 25 U.S.C. §§ 3653(3), 3681.

32. Federal law also recognizes Cherokee Nation authority in the TJSA for multiple other purposes. *See, e.g.*, 25 U.S.C. § 4302(4)(B) (the Cherokee Nation's "jurisdictional areas" are equivalent to a "reservation" for purposes of receiving grants under the Native American Business Development, Trade Promotion, and Tourism Act of 2000); *id.* §§ 3201(b)(4), 3202(9), 3208(a) (the Cherokee Nation has authority to implement federal grants for treatment programs for victims of child sexual abuse within the Cherokee Nation jurisdictional area); *id.* §§ 3102, 3103(12), 3104(b)(2), (4) (recognizing the Cherokee Nation's interest in use of national forest lands and proceeds from sale of products of national forests within the Cherokee Nation jurisdictional area); *id.* § 3115 (providing that the Secretary of Interior can enter into cooperative agreements with tribes for the management of national forest lands in their jurisdictional areas); 40 U.S.C. § 523(b)(2) (recognizing the Cherokee Nation's jurisdictional area for purposes of transferring excess federal government owned lands into tribal trust status); *see also* 25 C.F.R.

§ 151.2(f) (treating the TJSA as its "reservation" for purposes of acquiring trust land for the Cherokee Nation).

33. For instance, an extensive "Law Enforcement Agreement Between and Among the Cherokee Nation, the United States of America, the State of Oklahoma, and Its Political Subdivisions, the Various Boards of County Commissioners, and Various Law Enforcement Agencies," dated July 8, 1992, creates an intergovernmental Cherokee Nation Law Enforcement Compact that establishes the terms for cross-deputization of federal, state, and tribal law enforcement personnel "within the boundaries of the Cherokee Nation." Law Enforc. Agmt. at 1. For purposes of the agreement, the "Cherokee Nation's boundaries" are depicted on a map attached to the Compact as the TJSA.

34. The State of Oklahoma and the Cherokee Nation have also entered into a "Motor Vehicle Licensing Compact Between the Cherokee Nation and the State of Oklahoma for Lands Located Within the Compact Jurisdictional Area of the Cherokee Nation," dated August 16, 2013. That Compact allows the Nation to license motor vehicles owned by citizens of the Cherokee Nation pursuant to Cherokee Nation Law within the "Compact Jurisdictional Area of the Cherokee Nation." It also defines the boundaries of the "Compact Jurisdictional Area of the Cherokee Nation" by reference to a map attached to the Compact, depicting the same TJSA referenced in paragraph 22 above.

35. Similarly, the TJSA is recognized by the Cherokee Nation as territory in which the Cherokee Nation has governmental authority to administer tribal programs and to exercise sovereign rights.

36. The Constitution of the Cherokee Nation defines the boundaries of "the Cherokee Nation territory" as "those described by the patents of 1838 and 1846 diminished only by the

Treaty of July 19, 1866, and the Act of March 3, 1893." Cherokee Const., Art. II. That area is co-extensive with the TJSA described above.

37. The TJSA is "Indian country" under 18 U.S.C. § 1151(a) because it is an undiminished reservation which was established by the Treaty of New Echota, 7 Stat. 478 (Dec. 29, 1835), and whose final boundaries were established by the 1866 Treaty of Washington, 14 Stat. 799 (July 19, 1866), an area that is coextensive with the TJSA.

38. The Code of the Cherokee Nation asserts the Cherokee Nation's jurisdiction over activity within the TJSA for multiple purposes. For instance, Title 27, Ch.1 § 104 of the Cherokee Nation Code states that "[f]or purpose[s] of enforcing the provisions of the Cherokee Nation Environmental Act, the Cherokee Nation shall have jurisdiction in the territorial boundaries of the Cherokee Nation as defined in the Patent of 1838." See also Title 33, Ch.1 § 3(5) (defining authority of Cherokee Nation Housing Authority); Title 68, Ch. 9 §§ 102, 103(4) (imposing tax on waste "generated outside the original territorial jurisdiction of the Cherokee Nation," which is described as "all land within the fourteen (14) county area of northeastern Oklahoma as defined by the treaties of 1828, 1833 and 1835 and the Patent of 1838."); Title 68, §1353 (imposing motor vehicle licensing requirement on vehicles "within the reservation boundaries of Cherokee Nation").

39. Defendants have substantial contacts and business relationships with the Cherokee Nation, the citizens of the Cherokee Nation, employees of the Cherokee Nation, and/or Cherokee Nation businesses. Defendants have purposefully availed themselves of business opportunities within the TJSA. This includes activities in communities of high Cherokee Nation citizen population density that have a unique and undeniable tribal character.

II. Causes of Action Based on Consensual Relationships

40. In addition, the Cherokee Nation has jurisdiction over causes of action arising from the conduct of non-Indians within the TJSA when that conduct is (1) based on consensual relationships between the Cherokee Nation and non-Indians; and (2) threatens or has some direct effect on the political integrity, the economic security, or the health or welfare of the Cherokee Nation.

41. Defendants' manufacturing and distribution activities, marketing activities, and conduct, which have predominantly been actions undertaken by non-Indians within the TJSA, such as distributing opioids intended for pharmacies and patients located in the TJSA, directing opioid marketing materials into the TJSA, and conducting sales activities in the TJSA, have threatened and continue to threaten the economic security and the health and welfare of the Cherokee Nation through their promotion of the opioid epidemic.

III. Causes of Action Arising Out of Threats to the Cherokee Nation

42. Finally, the Cherokee Nation has jurisdiction over causes of action arising from conduct that threatens or has some direct effect on the political integrity, the economic security, or the health and welfare of the Cherokee Nation.

43. Defendants' conduct has caused and is causing a health crisis in the Cherokee Nation that threatens the health, welfare, economic security, and political integrity of the Cherokee Nation and all of its citizens. As a result of Defendants' actions, the citizens of the Cherokee Nation have become addicted to prescription opioid drugs. That addiction has caused children to be born addicted to prescription opioids and other controlled substances, as well as other short-and long-term emotional and physical damage that requires treatment, long-term care, and in some instances foster care or adoption. Many cases have required rehabilitation and

medical treatment for substance use disorder. Other cases have led to serious injury or death. The process of dealing with those effects has placed an enormous financial burden on the Cherokee Nation.

44. The negative impacts on the next generation of Cherokee Nation citizens caused by Defendants' conduct threaten the continuation of Cherokee Nation culture, identity, and effective self-government. These impacts are so severe, cumulatively, that Defendants' conduct threatens to destroy the Cherokee Nation.

FACTS COMMON TO ALL CLAIMS

I. The Prescription Opioid Crisis

45. Opioid literally means "opium-like," and the term includes all drugs derived in whole or in part from the opium poppy. Opioid drugs are also commonly referred to as narcotics.

46. The United States Food and Drug Administration's ("FDA") website describes prescription opioids as "powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks."[3] These medications can help manage pain when prescribed for the right conditions and when used properly in light of their inherent risks. But when misused or abused, they can cause addiction, overdose, and death.

47. Prescription opioids are not new, and have long been studied by the scientific and regulatory communities. For example, oxycodone has been in clinical use since 1917.[4] Another

[3] FDA, *Opioid Medications*, http://www.fda.gov/drugs/information-drug-class/opioid-medications (last visited Nov. 4, 2019).
[4] Eija Kalso, *Oxycodone*, 29 J. PAIN AND SYMPTOM MGMT. S47, S47 (May 2005).

common prescription opioid, hydrocodone, has been in clinical use in Europe since 1924 and was originally approved by the FDA in 1943.[5]

48. Through the mid-1990s, there was no opium epidemic. Opioid pain medications, to that point, were primarily prescribed to treat (i) acute pain, typically defined as pain that persists beyond the normal time of healing, or pain that lasts for less than three months,[6] and (ii) cancer pain.[7] Opioid pain medications were not commonly prescribed to treat "chronic pain," or non-cancer related pain that lasts for more than three months.

49. Physicians were reluctant to prescribe opioid drugs for chronic pain out of concern that this would lead to patient abuse and addiction. The dangers of opioid addiction were well known among physicians. In his book on cancer pain written approximately 60 years ago, Dr. Warren Cole, a surgeon, noted: "We must appreciate that severe constant pain will destroy the morale of the sturdiest individual. . . . But . . . we are often loathe to give liberal amounts of narcotics because the drug addiction itself may become a hideous spectacle."[8]

II. The Defendants' Conduct

50. Since at least the mid-1990s, Defendants have marketed, promoted, and sold opioid drugs in Oklahoma. Those drugs included their own branded opioid drugs, including (i) Duragesic, a transdermal patch that contained fentanyl; (ii) Ultram and Ultram Extended Release ("ER"), a tablet containing tramadol; (iii) Ultracet, a tablet containing tramadol and acetaminophen; (iv) Nucynta and Nucynta ER, a tablet containing tapentadol; (v) Tylenol with

[5] Drug Products Containing Hydrocodone; Enforcement Action Dates, 72 Fed. Reg. 55780, 55781 (Oct. 1, 2007).
[6] Task Force on Taxonomy of the International Association for the Study of Pain, CLASSIFICATION OF CHRONIC PAIN, xi (Harold Merskey & Nikolai Bogduk, eds.) (1994).
[7] U.S. Food & Drug Administration, Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse, https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm (last visited Nov. 4, 2019).
[8] Marcia L. Meldrum, *The Ongoing Opioid Prescription Epidemic: Historical Context*, 106 AM. J. PUB. HEALTH 1365 (Aug. 2016) (*quoting Opioids and Pain Relief: A Historical Perspective* 196, 198, 200-08 (Maria L. Meldrum ed., 2002)).

Codeine, a tablet containing acetaminophen and codeine; (vi) Tylox, a capsule containing acetaminophen and oxycodone.

51. Dr. Paul Janssen invented fentanyl in the 1950's. Fentanyl is a highly addictive opioid. Duragesic – which contains fentanyl – thus has a very high potential for abuse.

52. From the 1990s through at least 2016, Defendant Johnson & Johnson wholly owned two subsidiaries that, together, supplied other opioid manufacturers with ingredients to be used in opioid drugs. Those two subsidiaries were an important part of Defendants' pain management enterprise.

53. One of those subsidiaries – Tasmanian Alkaloids Limited ("Tasmanian Alkaloids") – cultivated and processed opium poppy plants to manufacture narcotic raw materials. The other subsidiary – Noramco, Inc. ("Noramco") – imported those narcotic raw materials into the United States, processed the materials into ingredients that could be used in opioid drugs, and sold the ingredients to other opioid manufacturers.

54. Johnson & Johnson acquired Noramco and Tasmanian Alkaloids in the 1980s in order to ensure a secure, reliable source of narcotic raw materials for its medications associated with Tylenol with Codeine.

55. Until 2016, Noramco and Tasmanian Alkaloids were key parts of Defendants' "pain franchise," which included all of Defendants' pain products. That role entailed a close relationship between Defendants and the two subsidiaries. For instance, Noramco employees did not believe that Noramco maintained its own bank accounts that were separate from Defendants' treasury. Defendants also shared employees and resources with Noramco and Tasmanian Alkaloids, and Noramco employees – who, by one description, were "with Johnson and

Johnson" – worked at Defendants' New Jersey facilities at times. Additionally, some employees held positions at multiple Johnson & Johnson companies at once.

56. Noramco and Tasmanian Alkaloids supplied opioid ingredients to other drug manufacturers in the U.S. such as Teva and Purdue Pharma. Those ingredients included oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone. At one point, Noramco had contracts "with all 7 of the top U.S. generic companies." By 2015, Noramco and Tasmanian Alkaloids had collectively become the top supplier for active ingredients in narcotic drugs in the U.S.

57. In 1994, Defendants, in concert with Tasmanian Alkaloids, "anticipated demand" for oxycodone. To meet that demand, Defendants' scientists at Tasmanian Alkaloids began a project "in order to develop a high thebaine poppy variety." That effort led to the creation of the "Norman Poppy," which Defendants internally described as "a transformational technology that enabled the growth of oxycodone."

58. Through Noramco, Defendants met the "anticipated demand" for opioids by selling opioid ingredients to other opioid manufacturers, such as Purdue Pharma. Noramco eventually grew to become the largest supplier of oxycodone, hydrocodone, codeine, and morphine in the United States.

59. In 1997, after seeing the success that Purdue Pharma had in marketing OxyContin for chronic non-cancer pain, Defendants relaunched their fentanyl-based Duragesic patch for the chronic, non-cancer market as well.

60. At the same time, Defendants embarked on a major marketing campaign. Using branded and unbranded marketing, they overstated the efficacy of opioids and spread the

message that pain was being undertreated. They also told consumers that "there was a low risk of abuse and a low danger" of prescribing opioids to treat chronic, non-malignant pain.

61. Those promotional efforts were designed to reach Oklahoma doctors, including those within the TJSA, in several ways. That included "education" from Defendants' sales representatives, literature funded by Defendants in medical journals and publications, materials from professional societies and patient advocacy groups, continuing medical education funded by Defendants, and lectures given by speakers who were paid by Defendants. It also included dinners and presentations for doctors, as well as partnerships with third-party advocacy and academic groups for seminars, symposia, and conferences. Each of those efforts was intended to influence the prescribing behavior of physicians and, in turn, increase Defendants' profits from opioids.

62. To help overcome skepticism towards liberal opioid prescribing practices, Defendants pushed the idea that chronic pain was undertreated. Their unbranded marketing campaigns, for example, often focused on "[h]eightening awareness of the under treatment of pain and its consequences." Defendants trained their Oklahoma sales representatives – including, based on information and belief, those representatives assigned to counties within the TJSA – on how to use these campaigns, including through use of "emotional selling" for opioids by convincing physicians that undertreated pain was harming patients.

63. Another unbranded marketing message that Defendants used to accomplish the "[b]ehavior [c]hange" of "increase[d] opioid use" was that undertreated acute pain inevitably would turn into chronic pain. Defendants emphasized this message in their marketing materials that promoted opioids as a class of drug.

64. Defendants also used the phrase "pseudoaddiction" to convince physicians that patients who exhibited signs of addiction – such as asking for "higher and higher doses" of opioids or returning to the physician before a prescription was scheduled to run out – were not actually suffering from addition, but from the undertreatment of pain. The solution, according to Defendants' marketing, was to prescribe the patients more opioids.

65. Defendants repeatedly promoted the concept of "pseudoaddiction" in various publications and in various media, including on an unbranded website called Prescribe Responsibly. Information on the Prescribe Responsibly website promoted Defendants' messaging that the solution to "pseudoaddiction" was "to prescribe more opioids."

66. Another unbranded marketing initiative that Defendants used was the dissemination of a brochure, titled "Finding Relief." That brochure, which was widely disseminated, did not differentiate between different kinds of opioids, promoted the idea that pain was undertreated, and downplayed any risk associated with opioids.

67. In addition to influencing doctors, Defendants employed strategies to influence a wide range of government agencies, through messages aimed at "optimizing the benefits of prescription opioids for pain management [and] minimizing their risks," including the risk of addiction, abuse, and diversion.

68. Defendants used a sales force in Oklahoma – including, based on information and belief, in the counties located within the TJSA – to promote, market, and sell various opioids. Those included the branded drugs that Defendants themselves manufactured: Duragesic, Ultram, and Nucynta.

69. Defendants' training of their sales representatives in Oklahoma included teaching sales representatives to avoid the so-called "addiction ditch." Avoiding the "addiction ditch"

meant that sales representatives were instructed to avoid any talk of the negative effects of opioid use – like addiction – and emphasize the purported positive effects during sales calls. To do so, Defendants urged their sales force to rely on a study by Dr. Russell Portenoy to "create dialogue about Opiophobia as a barrier."

70. As part of that training, Defendants trained their sales representatives that there was a 2.6% or lower risk of addiction when using opioids prescribed by a doctor. This was not true. As part of the same training, Defendants trained sales representatives to "establish that moderate to severe acute pain continues to be undertreated."

71. Defendants trained their sales representatives to target high-opioid-prescribing physicians, including pain specialists and primary care physicians. Defendants particularly targeted primary care physicians with their opioid marketing, identifying them as "Key Customer[s]" for Defendants' pain franchise.

72. Defendants' Oklahoma call notes show that sales representatives distributed visual aids that relied on Defendant-funded scientific studies on opioid use. Those call notes also show that Oklahoma sales representatives cited those studies over 1,000 times in sales visits to Oklahoma physicians – including, based on information and belief, physicians in counties within the TJSA – between 1998 and 2004. Those studies were later discredited by the U.S. Food and Drug Administration, which described them as false and misleading.

73. Defendants also failed to train their representatives on how to identify red flags that might indicate a "pill mill." For instance, sales representatives were never instructed to notice warning signs like patients lined up outside the door or patients passed out in a waiting room.

74. Instead, Defendants focused their efforts on aggressively marketing their addictive products. Sales representatives, for instance, used a coupon program as a marketing tool for Duragesic. They also used sample voucher programs, in which a sales representative delivered to a physician a "sample voucher for a box of 25 mcg or 50 mcg patches redeemed at pharmacy for a free 15-day trial" of Duragesic.

75. Defendants' sales representatives called on Oklahoma medical professionals, including, on information and belief, those within the TJSA, hundreds of thousands of times while selling opioids. During those calls, representatives often bought those professionals breakfast, lunch, coffee, and snacks. They also used speaker programs to entice physicians and encourage them to prescribe more opioids.

76. At the same time, Defendants made substantial payments to different pain advocacy groups that influenced prescribing physicians and other health care professionals. Those organizations include the American Academy of Pain Medicine ("AAPM"), the American Pain Society ("APS"), the American Pain Foundation ("APF"), the American Geriatrics Society, American Chronic Pain Association, National Pain Foundation, Pain and Policies Study Group ("PPSG"), the Pain Care Forum, the American Society of Pain Management Nursing, the American Academy of Pain Management/Academy of Integrative Pain Management ("AIPM"), the Center for Practical Bioethics, and the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO").

77. Two of those organizations – the AAPM and the APS – issued a "Consensus Statement" in 1996. That Statement was drafted in part by Robert Angarola, an attorney who had previously represented Defendants on opioid-related issues. Other drafters or consultants on that statement included David Haddox, a former medical director at Purdue; David Joranson, the

founder of PPSG; Richard Payne, a key opinion leader, or "KOL," and the co-leader of Defendants' National Pain Education Council ("NPEC") program; Matthew Midcap and Daniel Carr, both of whom had a financial relationship with Defendants; and Dr. Portenoy, who produced later-discredited studies on the low risks of opioid addiction.

78. The Consensus Statement suggested that pain is undertreated, and, as a result, that physicians should prescribe more opioids. It also characterized the dangers of opioid addiction and diversion as mere "impediments" to widespread opioid use. Defendants actively promoted the Consensus Statement, repeating its statements in its marketing efforts.

79. Another aspect of Defendants' marketing involves medical evaluation activities, including the creation and funding of the NPEC, which provided physicians with continuing medical education (CME) training on opioids and related pain products. Those CMEs targeted primary care physicians, pain specialists, oncologists, residents, nurses, and pharmacists. In Defendants' 2003 Business Plan Strategy for Duragesic, Defendants described NPEC as serving "to benefit not only DURAGESIC but also all future Janssen pain products."

80. Defendants did not let science stand in the way of that aim. For instance, CME materials for Defendants' NPEC program in 2002 disseminated false and misleading information regarding opioids and pain management. That 2002 program was designed to reach – and did reach – primary care physicians, pain specialists, oncologists, residents, nurses, and pharmacists.

81. At the same time, Defendants resisted any effort to stem the flow of opioids into patients' hands. When agencies within the State of Oklahoma began the process to schedule tramadol, for instance, Defendants characterized the move as a "threat" and consulted a physician who recommended that Defendants "mobilize" and send a "'swat' team."

82. Nor were Defendants deterred by the fact that their marketing was false, deceptive, or misleading. Defendants had ample notice that they were spreading misinformation.

83. One warning came from Defendants' own scientific advisory board. In 2001, that board advised Defendants that many of the messages Defendants had used to promote opioids were misleading and recommended that those messages should not be disseminated. Specifically, Defendants were advised not to market opioids, including fentanyl-based Duragesic, using messages related to abuse or with claims about supposedly low abuse potential. Defendants were also advised that no data existed that could support these claims, including the data that Defendants had themselves relied on. Additionally, Defendants were advised that aggressively marketing OxyContin on the same basis was what had gotten Purdue "in trouble," that minimizing the risk of abuse of Duragesic was "dangerous" due to its lethal nature, and that an increase of Duragesic sales would surely cause an increase in abuse of and addiction to the drug. The board's conclusion was clear: "Do not include the abuse message. Do not sell opioids on the abuse issue." Defendants continued anyway.

84. Other warnings came from the FDA. In 1998, the FDA found that three different convention posters used to promote Duragesic were "false and misleading" in numerous ways. The FDA pointed out that Defendants' statements as to the comparative efficacy of Duragesic were unsupported, that Defendants had taken data out of context to deliver misleadingly incomplete impressions, promoted unapproved uses, emphasized "chronic pain" indications without limitations or restrictions, and deceptively minimized risks and safety issues.

85. In 2004, the FDA sent Defendants a letter stating that a professional file card that Defendants used to promote Duragesic contained "false or misleading claims about the abuse potential and other risks of [Duragesic], and include[d] unsubstantiated effectiveness claims for

Duragesic." The FDA found that the Duragesic file card misbranded the drug by "suggesting that Duragesic has a lower potential for abuse compared to other opioid products," and "the file card could encourage the unsafe use of the drug, potentially resulting in serious or life-threatening hypoventilation."

86. The same year, the FDA also found that Defendants' suggestion that Duragesic was "less abused than other opioid drugs" was "false or misleading." Specifically, the agency found that it was "not aware of substantial evidence or substantial clinical experience to support this comparative claim," and that Defendants' "data cannot provide a basis for a valid comparison" among other opioid products. The FDA also noted that Defendants' data did not come from "a clinical database," but a "national public health surveillance system that monitors drug-related emergency department visits and deaths." As a result, the FDA concluded that Defendants' file card made "false or misleading safety claims and unsubstantiated effectiveness claims for Duragesic" in violation of 21 U.S.C. § 352(a).

87. The FDA also requested that Defendants "immediately cease the dissemination of promotional materials for Duragesic the same or similar to those described" in the 2004 letter. And it noted that "the violations discussed" in the letter did not "necessarily constitute an exhaustive list," and emphasized that it was Defendants' responsibility to "ensure that [its] promotional materials for Duragesic comply with each applicable requirement of the Act and FDA implementing regulations."

88. The file card was not the only piece of marketing that contained these materials, either. Many other promotional materials that Defendants used in Oklahoma – including, based on information and belief, in counties within the TJSA – contained the same false and misleading

messaging as the file card. Sales representatives used a variety of visual aids distributed within Oklahoma and the TJSA that included identical false and misleading messages.

89. Defendants' marketing materials repeatedly used letters and studies in deceptive ways to support misleading claims that downplayed the risk of addiction and overstated the efficacy of opioids.

90. Defendants also targeted high-prescribing doctors in Oklahoma – some of whom, based on information and belief, practiced within the TJSA – including those who faced disciplinary proceedings or criminal prosecutions.

91. It was no coincidence that opioid-related deaths and overdoses within Oklahoma increased as Defendants ramped up their aggressive marketing campaign. As one physician has testified in a related case against Defendants, the increase in opioid overdose deaths and opioid addiction treatment admissions in Oklahoma was caused by the oversupply of opioids through increased opioid sales and overprescribing since the late 1990s.[9]

92. Terri L. White, Commissioner of the Oklahoma Department of Mental Health and Substance Abuse Services, said the same thing. In 2019, Commissioner White opined that the oversupply and "significant widespread rapid increase in the sale of opioid prescription medications" beginning in the mid-1990s caused the "significant rise in opioid overdose deaths" and "negative consequences" associated with opioid use, including addiction, opioid use disorder, high rates of neonatal abstinence syndrome, and children entering the welfare system.

93. The President's Commission on Combatting Drug Addiction and the Opioid Crisis found the same causal link between the nationwide opioid crisis and the type of deceptive practices that Defendants used to sell their products. In fact, Defendants engaged in many of the

[9] Judgment After Non-Jury Trial ¶54, *Oklahoma v. Purdue Pharma L.P.*, No. CJ-2017-816 (Okla. Aug. 26, 2019).

practices that the Commission identified as "Contributors to the Opioid Crisis." They relied on medical materials to make "unsubstantiated claims." They failed to use "[h]igh quality evidence demonstrating that opioids can be safely used for chronic non-terminal pain." They underwrote organizations like APS and JCAHO, both of which produced materials stating that "pain [i]s the 'fifth vital sign.'" And they funded other groups that aggressively opposed federal prescription-opioid regulations.

94. Tragically, it worked. By 2001, a significant number of Oklahoma physicians, the healthcare community, law enforcement, medical advisory boards, and others were being marketed to and misled about opioids. Dr. Terrell Phillips, for instance, gave a CME presentation to the Oklahoma State Medical Association ("OSMA") in October 2016 about how to avoid addiction in pain management. He explained that "[e]verybody knows how we got into this situation":

> They told us we were underprescribing. We need to prescribe more. It's the patient's rights to have pain medicine, so we all got on board. And when someone said they were hurting, we said, Okay, we are going to give you something. Now it's just the opposite. Not everyone deserves pain medicine.

95. Despite the misery that Defendants unleashed, the effects of their conduct can be abated in Oklahoma and the TJSA.

96. The President's Commission on Combating Drug Addiction and the Opioid Crisis found that "[h]istorical precedent demonstrated that this crisis can be fought with effective medical education, voluntary or involuntary changes in prescribing practices, and a strong regulatory and enforcement environment."

97. Commissioner Terri White has said the same thing. Commissioner White has testified that the opioid crisis in Oklahoma – including Defendants' false and misleading marketing of their drugs and opioid products generally – can and "must be abated."

III. The Defendants' Failure to Prevent Opioid Diversion

98. In parallel with the popularization of opioid drugs through, among other things, Defendants' relentless marketing campaign, the federal government recognized there was a need to tightly regulate opioids to ensure these powerful drugs were only distributed to patients with a legitimate medical need. The Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.*, ("CSA"), was originally enacted in 1970 to ensure that dangerous and addictive drugs, including prescription opioids, would be carefully monitored and regulated on the market.

99. The CSA creates a legal framework for manufacturing distributing controlled substances. Congress passed the CSA partly out of a concern about the widespread diversion of controlled substances out of legitimate channels and into the illegal market. *See* H.R. Rep. No. 91-1444, (1970), reprinted in U.S.C.C.A.N. 4566, 4572.

100. Prescription opioids with a high potential for addiction, or for which abuse may lead to severe psychological or physical dependence, are categorized under Schedule II of the CSA and the corresponding regulations. *See* 21 C.F.R. §1308.12. Drugs listed on Schedule II include non-synthetic derivatives of the opium poppy (such as codeine and morphine, which are also called "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

101. To prevent unauthorized users from obtaining opioids, the CSA creates a distribution monitoring system for controlled substances. At the heart of this system are registration and tracking requirements imposed upon any person or entity authorized to handle controlled substances.

102. The supply chain for prescription opioids, regulated under the CSA, begins with the manufacture and packaging of the pills. The manufacturers, such as Defendants, then transfer the pills to distribution companies, which then supply opioids to hospitals, pharmacies, doctors, and other healthcare providers, which in turn dispense the drugs to patients. A manufacturer like Defendants is thus regulated both as a manufacturer under the CSA when it produces and packages opioids drugs and as a distributor when it ships the pills to the next party in the supply chain.

103. Each participant in the supply chain shares the responsibility for controlling the availability of prescription opioids and has a duty to evaluate the party to whom it is providing opioids. Opioid "diversion" occurs whenever the drugs are transferred from a legitimate channel of distribution or use to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain, including at the point of original shipment by a manufacturer such as Defendants. When a manufacturer ships the opioids, it assumes those duties imposed on distributors since the manufacturer, at that point in the supply chain, is itself distributing the drugs.

104. For example, at the level of manufacturing and distribution, diversion occurs whenever manufacturers allow opioids to be lost or stolen in transit, or by filling suspicious orders of opioids from wholesale distributors or pharmacies. Suspicious orders include orders of an unusually large size, orders that are disproportionately large in comparison to the population of a region served by the wholesale distributors or pharmacies, orders that deviate from a normal pattern, and/or orders of unusual frequency.

105. Defendants, as manufacturers and distributors under the CSA, have a number of duties that it must fulfill under the CSA to prevent diversion, of which the most important are

ensuring the physical security of opioid drugs and maintaining robust records of every shipment of opioids it produces.

106. All opioid distributors – including Defendants, which are not only manufacturers, but are also regulated as distributors under the CSA whenever it ships the opioids it has produced – are required to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, manufacturers and distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

107. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system which monitors the flow of Schedule II controlled substances from their point of manufacture through commercial distribution channels to the point of sale. ARCOS accumulates data on manufacturers' and distributors' controlled substances acquisition/distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS-reportable controlled substances, which includes Defendants, must report its distribution and acquisition transactions to the DEA.

108. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, *e.g.*, by purchase or transfer, return from a customer, or supply by the federal government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by government agencies) for

each ARCOS-reportable controlled substance. *See* 21 U.S.C. § 827(d)(l); 21 C.F.R. §§ 1304.33(d), (e). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

109. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain on a current basis a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. *See* 21 U.S.C. § 827(a)(3); 21 C.F.R. §§ 1304.21(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

110. In order to maintain registration, manufacturers and distributors must also maintain effective controls against diversion of controlled substances. When determining if a manufacturer and/or distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. *See* 21 C.F.R. § 1301.71.

111. To combat the problem of opioid diversion, the DEA has provided guidance to manufacturers and distributors on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions.

112. Since 2007, the DEA has hosted at least five conferences to provide registrants with updated information about diversion trends and regulatory changes that affect the drug supply chain, the distributor initiative, and suspicious order reporting. All of the major manufacturers and distributors, including Defendants, attended at least one of these conferences. The conferences allowed the registrants to ask questions and raise concerns. Registrants could also request clarification on DEA policies, procedures, and interpretations of the CSA and implementing regulations.

113. Accordingly, the CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the ultimate patient or customer. Every person or entity who manufactures, distributes, or dispenses opioids must obtain a "registration" with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the licit to the illicit marketplace, and there is great potential for harm to the general public.

114. However, over time and despite the regulated controlled substances supply chain under the CSA, opioid diversion now occurs in the United States at an alarming rate, including throughout the TJSA. In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

115. In fact, in addition to the CSA and its associated regulations intended to control the flow of opioids, the DEA formed a specific division to address diversion issues – the Diversion Control Division – with a stated mission "to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs."

116. The issue of diversion is directly linked to, and is a result of, Defendants' marketing barrage. In a 2006 policy statement issued by the DEA and the Diversion Control Division, the linkage between increased marketing and the diversion of opioid drugs was explicitly acknowledged: "The large amount of [the drug] available in the marketplace may have increased opportunities for abuse and diversion. Both DEA and [the manufacturer of the drug]

have stated that an increase in a drug's availability in the marketplace may be a factor that attracts interest by those who abuse and divert drugs."

117. Given their trusted role in the controlled substance supply chain, manufacturers such as Defendants are acutely aware of the opioid diversion issue, particularly given the granular data they possess about the ultimate distribution of their drugs, which includes both the data required to be submitted to ARCOS and their own internal data analysis systems.

118. Given Defendants' legal requirements under the CSA, including its reporting obligations, and its vast data collection and analysis capabilities enabling it to identify opioid diversion, Defendants should have identified opioid diversion activities in the TJSA and taken actions to limit the flow of opioids into the TJSA to prevent diversion.

IV. Defendants Concealed Misrepresentations About the Risks of Opioids

119. Defendants profited from its misrepresentations about the risks and benefits of opioids for chronic pain, even though it knew that its marketing was false and misleading.

120. The history of opioids, as well as research and clinical experience over the past three decades, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms that came from long-term opioid use. And more recently, the FDA and CDC have publicly stated that many claims about the low risks long-term opioid use are wholly untrue.

121. But despite knowing that opioids are dangerous, Defendants took steps to avoid detection and to fraudulently conceal its deceptive marketing and unlawful fraudulent conduct. It disguised that conduct by working through front groups like the AAPM and the APS, as well

as by working through unbranded marketing, third-party advocates, and professional associations.

122. Additionally, Defendants affirmatively assured the public, state and local governments, and tribal nations such as the Cherokee Nation, that it was working to prevent diversion and to curb opioid use and abuse. But it failed to do anything of the sort – indeed, it actively tried to defeat those aims through its front groups.

123. Defendants thus successfully concealed from the medical community, patients, and the Cherokee Nation any facts that would have aroused suspicion of the claims that the Cherokee Nation now asserts. The Cherokee Nation did not know of the existence or scope of Defendants' fraud and could not have acquired such knowledge through the exercise of reasonable diligence.

CLAIMS

COUNT ONE
Nuisance

124. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1-123.

125. Defendants unreasonably and significantly interfered with the Cherokee Nation's public health, safety, peace, and public comfort through their role in deceptively and improperly marketing and promoting opioid drugs, which has resulted in high rates of addiction, overdose, and injuries threatening the fabric of Cherokee society. Defendants' unreasonable conduct violates regulations and professional guidelines, in addition to their legally prescribed duties regarding accurate branding and marketing of its drugs under the Federal Food, Drug, and Cosmetics Act.

126. Defendants' conduct directly and proximately caused injury to the Cherokee Nation. Namely, that conduct has led to increased crime and property damage within the

Cherokee Nation. Approximately 70 to 80 percent of the crimes that lead to conviction of Cherokee Nation citizens are drug related. In recent years, a majority of these drug-related crimes were related to prescription opioid drugs. Prescription opioid abuse has caused a substantial increase in the amount of thefts, burglaries, assaults, batteries, child abuse or neglect, DWIs, public blight, and vagrancy. It has also led to high rates of addiction and overdose within Cherokee Nation communities, which threatens the fabric of Cherokee Nation society.

127. Defendants' conduct has caused the Cherokee Nation unique harm that is different from that suffered by Cherokee Nation citizens. Specifically, the Cherokee Nation has been harmed in its proprietary interests. As a result of Defendants' conduct, the Cherokee Nation cannot fully sustain its political and cultural integrity in the face of the opioid epidemic caused by Defendants.

128. The effects of the nuisance can be abated, and the further occurrence of such harm and inconvenience can be prevented. Defendants have a responsibility to do so.

COUNT TWO
Fraud

129. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1-128.

130. Defendants, individually and acting through its employees and agents, made misrepresentations and omissions of facts material to the Cherokee Nation and its residents to induce them to purchase, administer, and consume opioids as set forth in detail below.

131. Defendants knew at the time that it made its misrepresentations and omissions that they were false but nevertheless continued to market and advertise highly addictive opioids to residents of the Cherokee Nation, who relied on the information provided by Defendants.

132. Defendants intended the Cherokee Nation and its residents to rely on its misrepresentations and omissions so that they might continue to turn a profit.

133. The Cherokee Nation reasonably relied on Defendants' misrepresentations and omissions as information promulgated by a pharmaceutical company with a legal duty to provide truthful information about opioid drugs.

134. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, the Cherokee Nation and its residents suffered actual financial damage. The Cherokee Nation has been forced to devote more of its resources to addiction-related problems, thereby leaving a diminished pool of available resources to other societal concerns, such as education and cultural preservation.

135. Defendants' conduct in knowingly and intentionally marketing opioid drugs in a deceptive and unfair manner was willful, wanton, and malicious and was directed at the public generally.

COUNT THREE
Negligence/Gross Negligence

136. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1-135.

137. Defendants negligently marketed and misbranded opioids in violation of its duty pursuant to the Federal Food, Drug, and Cosmetic Act by producing and disseminating misleading and deceptive advertising about the risks and dangers of opioid drugs, which created a foreseeable injury to the Cherokee Nation by threatening the health, safety, and welfare of the Cherokee Nation and its citizens.

138. Defendants were also negligent *per se* based upon its violations of the Federal Food, Drug, and Cosmetic Act by introducing misbranded drugs into interstate commerce.

139. Defendants' negligent conduct was the direct and proximate cause of injury to the Cherokee Nation and its citizens.

140. Defendants' negligent conduct damaged the Cherokee Nation and its citizens, including damages to the health, safety, and welfare of the Cherokee Nation and its citizens.

COUNT FOUR
Unjust Enrichment

141. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1-140.

142. As an expected and intended result of Defendants' wrongdoing, it has profited and benefited from saturating Cherokee Nation society with highly addictive opioid painkillers that have been deceptively and unfairly marketed to the Cherokee Nation and its citizens, and which have caused injury to the Cherokee Nation.

143. Defendant has been unjustly enriched at the expense of the Cherokee Nation.

COUNT FIVE
Civil Conspiracy

144. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1-143.

145. Defendants (1) associated with one or more persons to further an unlawful objective, including deceptive and unfair marketing of opioid drugs, via an agreement, understanding, or "meeting of the minds" regarding the objective and the means of pursuing it; (2) committed an unlawful act in furtherance of the agreement; and (3) proximately caused harm as a result of its actions.

PRAYER FOR RELIEF

WHEREFORE, the Cherokee Nation prays that the Court grant the following relief:

(a) Injunctive relief;

(b) Civil penalties;

(c) Compensatory damages;

(d) Restitution;

(e) Punitive damages;

(f) Attorneys' fees and costs; and

(g) All such other relief this Court deems just and fair;

(h) Plaintiff seeks a trial by jury for all counts so triable.

DATED: November 21, 2019

Respectfully Submitted,

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